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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/283,318	03/31/1999	JACK V. SMITH		9827

7590 09/09/2003  
JACK V SMITH  
P. O. BOX 156  
ARDEN, NC 28704

EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/09/2003

*Handwritten signature/initials*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/283,318

Applicant(s)

SMITH, JACK V.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 03 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19- 32 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23- 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

The Examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Hill.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 25, 2003 has been entered.

Claims 23- 29 are under consideration.

#### ***Claim Rejections - 35 USC § 112***

Claims 23- 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims were rejected because it appeared that the test strip would always give a positive result and it was not clear what "means" intended.

Applicant argues that the secret of dry chemistry technology is that the strips are kept dry. Applicant asserts that the specification clearly states that if HIV antibody is present in the sample then it complexes with antigen-enzyme complex, there is less enzyme activity and less color develops.

Applicant's arguments have been fully considered and not found persuasive.

Applicant has amended the claims 23 and 27 to remove the first recitation of "means" but there is still an additional "means" in each claim. This is still not as explained in the prior action.

Applicant asserts in the response (page 4, lines 9- 13) that the specification clearly states that if HIV antibody is present in the sample then it complexes with antigen-enzyme complex, there is less enzyme activity and less color develops. Applicant is requested to point to the particular part of the specification that supports the claim in respect to the reaction of the enzyme/antibody in the sample as Applicant indicates that it is clearly stated because the Examiner fails to find it. To the contrary in the disclosure Example 7, it appears that color is produced when the dipstick is exposed to anti-HIV. The claims do not indicate a relationship between indicator color and antibody concentration. It is still not clear how the test functions.

***Claim Rejections - 35 USC § 102 and 103***

The rejections are withdrawn; however, it is noted that several of the differences asserted by Applicant are commensurate with the claims. The claims do not exclude

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total immersion of test stick in sample or define a range for the amount of sample tested.

### ***New Rejections***

Claims 23- 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the correlation between color and antibody concentration is. Does increase in color indicate more antibodies? This needs to be indicated in the claims. Furthermore, it is not clear how the claimed assay cannot be ELISA if it uses enzyme and detection substrate. A dictionary definition of ELISA is provided. The definition indicates 'wells' are coated. In this case, antigen is "bound" to thin surface serves an equivalent function as a 'well' and the enzyme, substrate, and detection are the same. The invention appears to claim an ELISA method practiced in the form of a dipstick/dot blot.

Claims 23- 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a labeled antigen used to detect antibodies against HIV.

The art recognizes labeled antibodies for use in detection and those are in wide use.

Example 7 discloses an assay to detect antibodies using labeled antigen applied to a thin layer and that the antibody concentration can be determined. They are no specific teachings on how the proteins (antibodies) are measured. The specification does not teach usefulness of knowing antibody concentration, does not teach what the standard of the color chart is, does not teach where the level of 10 fmol/L comes from or how this is verified, or teach that the assay has a certain sensitivity and specificity.

Carpenter is cited as art that homogenous assays are suited for measurement of drugs and haptens, that they are not in wide spread use and that they present special problems in the measurement of proteins (page 2, column 1, third paragraph).

Ray is cited as art that teaches that the rapid assays need to be specific and sensitive in order to be useful substitutes for more cumbersome, time consuming, and costly techniques.

Thus, the lack of working examples, lack of guidance in the specification as to quantitation, specificity, and sensitivity, and the unpredictability of the art and that the art teaches away from it, and greatly reduces the probability that one of skill in the art would successfully practice the claimed invention without undue experimentation.

### ***Conclusion***

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*WA*

Myron G. Hill  
Patent Examiner  
5 September 2003

*James C. Housel*  
JAMES HOUSEL 9/8/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600